DEC 16 2011

510(k) SUMMARY

Lanx, Inc's Cervical SA Intervertebral Body Fusion System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Lanx, Inc.
310 Interlocken Parkway, Suite 120
Broomfield, CO 80021

Contact Person: Michael Funk
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Date Prepared: October 12, 2011

Name of Device and Name/Address of Sponsor

Lanx Cervical SA System
Lanx, Inc.
310 Interlocken Parkway, Suite 120
Broomfield, CO 80021

Common or Usual Name

Intervertebral Body Fusion Device

Classification Name

21 CFR § 888.3080, Orthosis, spinal intervertebral fusion

Predicate Devices

Globus Coalition™ (K083389)
Medtronic PEEK PREVAIL™ (K094042)

Intended Use / Indications for Use

The Lanx Cervical SA System is a stand-alone cervical fusion device intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C3-T1) at one level. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment. The Lanx Cervical SA is to be filled with autogenous bone graft material, and is to be used with titanium alloy screws which accompany the implant.

Technological Characteristics

This submission is intended to seek clearance for the Lanx Cervical SA Intervertebral Body Fusion System ("Lanx Cervical SA System"). The product includes the Lanx Cervical SA PEEK implant models with titanium components for additional fixation.

All devices in the Lanx Cervical SA System are made of PEEK-OPTIMA® LT1 per ASTM F2026 and/or Titanium Alloy (Ti-6Al-4V ELI) per ASTM F136. The PEEK components include Tantalum markers per ASTM F560. The Lanx Cervical SA implants have a central cavity to accommodate bone graft, and transverse grooves to improve fixation and stability. Additional fixation and stability is provided by screws and plates which are made from an implant grade titanium alloy (Ti-6Al-4V ELI) meeting the requirements of ASTM F136. The device is available in a variety of different sizes and configurations to accommodate anatomical variation in different vertebral levels and/or patient anatomy. The Lanx Cervical SA System is provided non-sterile.

The Lanx Cervical SA System has the same or similar intended use and indications, principles of operation and technological characteristics as predicated devices. Mechanical testing and engineering analysis demonstrated comparable mechanical properties to predicate devices.

Performance Data

Performance testing for comparison of mechanical performance included tests per ASTM F2077 (static and dynamic compression, static and dynamic compression shear, static and dynamic torsion), ASTM F2267 (subsidence), ASTM expulsion testing draft standard Z8423Z (expulsion), Flexion/Extension testing, and wear debris analysis. In all instances, the Lanx Cervical SA System met acceptance criteria and functioned as intended.

Substantial Equivalence

The Lanx Cervical SA System has the same or similar intended uses, indications, technological characteristics, and principles of operation as the previously cleared Globus Coalition™ (K083389) and Medtronic PEEK PREVAIL™ (K094042). The intended use of the subject device and predicate devices contain the same range of levels treated, the same stand-alone indications, and the same implantation methods. The technological characteristics of the subject device are substantially equivalent to the predicate devices, as they all contain a variety of footprints and sizes to accommodate patient anatomy; are available in a range of heights, footprints, and lordotic angles; contain a screw fixation feature to accept at least two bone screws; and provide a mechanism to limit screw back out. Performance data demonstrate that the Lanx Cervical SA System does not raise any issues of safety or effectiveness; hence it is as safe and effective as the predicate devices. Thus, the Lanx Cervical SA System is substantially equivalent to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Lanx, Inc.
% Mr. Michael Funk
310 Interlocken Parkway, Suite 120
Broomfield, Colorado 80021

DEC 16 2011

Re: K112388
Trade/Device Name: Lanx Cervical SA Intevertebral Body Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE
Dated: November 7, 2011
Received: November 9, 2011

Dear Mr. Funk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K112388

Device Name: **Lanx Cervical SA Interbody Fusion System**

Indications for Use:

The Lanx Cervical SA System is a stand-alone cervical fusion device intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C3-T1) at one level. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment. The Lanx Cervical SA is to be filled with autogenous bone graft material, and is to be used with titanium alloy screws which accompany the implant.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112388